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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2015-0042]

Eligibility of the Republic of Poland to Export Poultry and Poultry Products to the United States

AGENCY: Food Safety and Inspection Service, USDA

ACTION: Notice and response to comments

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that the Republic of Poland (Poland) is eligible to export poultry products to the United States. FSIS has reviewed Poland's poultry laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the United States food safety inspection system for poultry products. Therefore, poultry products derived from poultry slaughtered and processed in certified Polish establishments are now eligible for export to the United States. All such products will be subject to reinspection at United States points-of-entry by FSIS inspectors.

APPLICABLE: Poland's poultry products eligible for import to the United States will be added to the FSIS Import Library (<https://www.fsis.usda.gov/importlibrary>) on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On April 20, 2016, FSIS published a proposed rule in the **Federal Register** (81 FR 23194) to add Poland to the list of countries in the regulations eligible to export poultry products to the United States. Between the publication of the proposed rule concerning Poland's eligibility and this **Federal Register** notice, FSIS finalized rulemaking (84 FR 65265; November 27, 2019) to remove the lists of foreign countries eligible to export meat, poultry, and egg products to the United States from its regulations and instead maintain a single list of eligible countries on FSIS' website at:

<https://www.fsis.usda.gov/importlibrary>. This change allows FSIS to better provide the public with the most accurate and current information. In addition, the final rule affected FSIS' process for implementing equivalence determinations. Instead of publishing proposed and final rules in the **Federal Register**, FSIS now implements equivalence determinations through **Federal Register** notices. The criteria FSIS uses to evaluate whether a foreign country is eligible to export meat, poultry, or egg products have not changed. FSIS continues to provide an opportunity for public comment when proposing through **Federal Register** notices to list new countries as eligible to export

products to the United States or to list existing countries as eligible to export certain new products.

As explained in the 2016 proposed rule to list Poland as eligible to export poultry products to the United States (81 FR 23194, April 20, 2016), under the PPIA and implementing regulations, poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States (21 U.S.C. 466). Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry products to the United States.

Paragraph 9 CFR 381.196(a) requires that the standards of a foreign country's poultry inspection system, its legal authority for the inspection system, and the regulations implementing the system be equivalent to those of the United States.

The country's inspection program must also impose requirements equivalent to those of the United States.

Evaluation of the Polish Poultry Inspection System

On April 20, 2016, FSIS published a proposed rule to determine, based on the results of audits in 2011 and 2014, that Poland's poultry inspection system is equivalent to the United States system and, therefore, to add Poland to the list of countries eligible to export poultry products to the United

States in the regulations. For more detailed information on the FSIS evaluation of the Polish poultry inspection system see the 2016 Poland proposed rule (81 FR 23194, April 20, 2016), and for the full 2011 and 2014 audit reports, go to:

<https://www.fsis.usda.gov/federal-register/rules/eligibility-republic-poland-export-poultry-products-united-states>.

On August 21, 2014, FSIS published the final rule Modernization of Poultry Slaughter Inspection (79 FR 49566, August 21, 2014). The rule created regulatory changes that apply to all poultry slaughter establishments and established a new optional post-mortem inspection system, the New Poultry Inspection System (NPIS). In 2016 and 2017, Poland sent letters to FSIS outlining the changes that were made to Poland's poultry inspection system to achieve equivalence with the new U.S. regulations. These included requirements that establishments have procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and procedures to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material throughout the entire slaughter and dressing operation. FSIS reviewed the submitted letters and additional information and determined on December 29, 2017, that Poland's poultry slaughter inspection system is equivalent to the U.S. system regarding the requirements in the final rule "Modernization of Poultry Slaughter Inspection."

Poland also is eligible to ship meat products to the United States. After the publication of the 2016 proposed rule

concerning Poland's equivalence for poultry, FSIS conducted an onsite audit in September 2017 to verify the ongoing equivalence of Poland's meat inspection system. Poland's 2017 onsite audit identified a finding related to government inspection personnel in certified establishments producing meat products for export to the United States and indicated that additional information was needed before making a final conclusion about whether Poland's meat products inspection system remained equivalent to that of the United States. Consequently, in 2018 during the review of Poland's comprehensive corrective action plans to address the 2017 audit finding, Poland's General Veterinary Inspectorate (GVI), which is Poland's central competent authority (CCA) in charge of food inspection, confirmed that the same inspection arrangement was used in poultry establishments that expressed interest in exporting to the United States. FSIS was concerned that contract personnel, rather than government personnel, may have been conducting inspection. In response to this information, in 2018 and 2019, Poland submitted corrective action plans that addressed FSIS' findings and ensured that government inspectors will be performing inspection activities at all slaughter and processing establishments that are eligible to export products to the United States. FSIS conducted an onsite audit from July 15 through August 1, 2019 and concluded that Poland had satisfactorily implemented the corrective action plans that it had submitted in response to the 2017 audit. For the most recent full audit reports, go to:

<https://www.fsis.usda.gov/news-events/publications/poland-foreign-audit-report>.

FSIS' Equivalence Determination

After considering the comments received on the proposed rule, discussed below, FSIS concludes that Poland's poultry inspection system is equivalent to the United States' inspection system for poultry products. Therefore, FSIS is announcing that Poland is eligible to export poultry products to the United States (9 CFR 381.196(b)). FSIS has added Poland to its list of eligible countries to export poultry products to the United States on its website at:

<http://www.fsis.usda.gov/importlibrary>.

Polish poultry products will be eligible for importation into the United States only if they are from birds slaughtered on or after the publication date of this **Federal Register** notice. Under FSIS' import regulations, the government of Poland must certify to FSIS that those establishments requesting to export poultry products to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)).

Upon publication of this **Federal Register** notice, Poland is eligible to export to the United States raw and processed poultry products derived from birds slaughtered in Poland. The eligible processing categories include: Heat Treated - Shelf Stable, Not Heat Treated - Shelf Stable, Fully Cooked - Not Shelf Stable, and Thermally Processed - Commercially Sterile.

Poland would need to submit additional information for FSIS to review and may need to undergo an additional audit before FSIS would allow Poland to export other raw and processed poultry products to the United States not listed above. FSIS maintains a country-specific webpage¹ on FSIS' website with a list of the process categories and the product groups Poland is eligible to export to the United States.

Although a foreign country may be listed on FSIS' website as eligible to export poultry products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States, including those of USDA's Animal and Plant Health Inspection Service (APHIS). These requirements include restrictions under 9 CFR part 94 of the APHIS regulations, which regulate the importation of poultry products from foreign countries into the United States to control the spread of specific animal diseases.

All poultry products exported to the United States from Poland will be subject to reinspection by FSIS at United States points-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

FSIS also will conduct other types of reinspection activities, such as physical inspection and incubation of thermally processed, commercially sterile (canned) products to ensure product safety and taking product samples for laboratory

¹ See: <https://www.fsis.usda.gov/inspection/import-export/import-export-library/poland>.

analysis to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter United States commerce. If a product does not meet United States requirements, it will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import reinspection activities can be found on the FSIS website at: <https://www.fsis.usda.gov/inspection/import-export/import-guidance>.

Finally, within one year of the publication date of this **Federal Register** notice, FSIS will conduct an on-site audit of Poland's poultry inspection system to verify ongoing equivalence. During the audit, FSIS auditors will verify that Poland's CCA has implemented its food safety inspection system as described in the Self-Reporting Tool (SRT) and supporting documentation. FSIS will audit government offices, establishments, and laboratories to verify that the CCA has implemented its inspection system as documented and verify that the country's system of controls remains equivalent to the U.S. inspection system.

Summary of Comments and Responses

FSIS received two comments in response to the proposed rule. The government of Poland supported the proposed rule and one consumer advocacy organization opposed it. The following is a brief summary of the relevant issues raised in the comments and FSIS' responses.

New Poultry Inspection System (NPIS)

Comment: A consumer advocacy group requested more information on how Poland demonstrated equivalence with the United States' regulatory requirements in the final rule "Modernization of Poultry Slaughter Inspection" (79 FR 49566, Aug. 21, 2014). Additionally, the consumer advocacy group questioned whether Poland would implement an inspection system similar to NPIS.

Response: As stated earlier, in 2016 and 2017, Poland sent letters to FSIS outlining the changes that were made to Poland's poultry inspection system to achieve equivalence with the FSIS' new regulations. These included requirements that establishments have procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and procedures to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material throughout the entire slaughter and dressing operation. FSIS reviewed the submitted letters and additional information from Poland and determined on December 29, 2017, that Poland's poultry slaughter inspection system is equivalent to the U.S. system regarding the requirements in the final rule, "Modernization of Poultry Slaughter Inspection."

Poland also explained in the letters that it does not plan to implement an inspection system like NPIS in any of its establishments. If Poland later chooses to implement NPIS, Poland will need to implement regulations for that inspection system equivalent to United States' NPIS regulations.

Audit Report Findings

Comment: The consumer advocacy organization expressed concern regarding the two audits of Poland's poultry inspection system. The organization argued that the 2011 audit revealed major issues with Poland's poultry inspection system that prevented FSIS from moving forward with rulemaking. According to the organization, the issues found in the 2014 audit are recurring problems from the 2011 audit.

Response: Poland responded to the FSIS' 2011 audit findings with comprehensive corrective action plans that addressed all of FSIS' audit findings. Consequently, FSIS conducted a follow-up initial equivalence audit in 2014 to assess the effectiveness of the implemented corrective actions. The FSIS auditors verified that Poland had effectively implemented the proffered comprehensive corrective action plan and that Poland met the equivalence criteria for all six components. The evaluation of all data collected before, during, and after the onsite audit shows that Poland's poultry inspection system is equivalent to the United States' inspection system for poultry.

Comment: The consumer advocacy organization also expressed concern regarding establishment-level findings during the second initial onsite audit. The consumer advocacy group stated that: (1) in one of the slaughter facilities, a Polish inspector was not performing post-mortem inspection of all carcasses for pathology, food safety issues, and defects; (2) in one of the slaughter facilities, blood was accumulating on the kill floor, leading to unsanitary conditions; (3) in one of the processing facilities, exposed product came into contact with the sides of a transporting cart and the floor; and (4) in one of the establishments, Polish inspection personnel did not issue non-compliance reports for the facility's failure to maintain verification records that meet HACCP recordkeeping requirements.

Response: The FSIS auditors deemed each of the findings highlighted by the consumer advocacy organization to be isolated incidents that have been addressed and resolved. In each case, the GVI ordered immediate corrective actions to address the findings. The CCA verified that the establishments made the necessary adjustments and provided supporting documents during and after the audit exit meeting. The auditors verified that the GVI had adequately and effectively implemented its corrective action plan and addressed the audit findings with immediate corrective action and preventive measures. FSIS' evaluation of Poland's proffered corrective actions and related implementation records provided to FSIS after the exit meeting, found that all audit findings were properly addressed.

Sample Size

Comment: The consumer advocacy organization questioned why FSIS visited only two poultry slaughter and processing establishments, two poultry processing (raw and ready-to-eat) establishments, and one poultry canning facility during the 2014 audit. According to the commenter, the number of establishments the auditor visited during the 2014 audit was not sufficient to verify that Poland addressed the findings from the 2011 audit.

Response: During onsite verification audits, FSIS visits foreign sites associated with the system that provides government oversight and inspection, including the establishments interested in exporting products to the United States, government offices, and government laboratories. The purpose of the audit is to verify that the implementation of the equivalence components of the country's food safety inspection system are consistent with its design documented by the CCA in the SRT. FSIS assesses the food safety inspection system as a whole, by verifying controls and by recognizing that any findings identified during the audit need to be considered in the context of the overall food safety inspection system. In the 2011 Poland audit, FSIS audited two processing facilities and one cold storage facility. During the 2014 audit, FSIS audited five poultry establishments, which were all the establishments intending to export product to the United States at that time. These establishments included two slaughter and processing establishments, and three processing only establishments,

including the canning facility that FSIS audited in 2011. Because of the number and types of establishments audited during the 2014 audit, FSIS is confident that the number of establishments audited was sufficient to verify that Poland had addressed the findings from the 2011 audit.

Time between Final Audit and Publication of the Proposed Rule

Comment: The consumer advocacy organization questioned the accuracy of the information presented in the proposed rule because, according to the commenter, too much time passed between the final audit and publication of the proposed rule.

Response: The time between the final audit (2014) and the proposed rule is consistent with that for other equivalence determinations since 2007. Further, FSIS intends to conduct an audit of Poland within one year of its equivalence becoming effective. FSIS will continue to conduct annual records reviews of Poland's poultry inspection system and all imported product from Poland will be reinspected once it enters the United States. Therefore, FSIS will effectively ensure Poland meets equivalence requirements on an ongoing basis.

Trade

Comment: The consumer advocacy group stated that the proposed rule was one piece of the larger Transatlantic Trade and Investment Partnership (TTIP) negotiations and that the safety of U.S. consumers was being sacrificed for expanded trade.

Response: FSIS makes determinations of equivalence by evaluating whether foreign food inspection systems attain an equivalent level of protection provided to our domestic system; FSIS determinations for Poland are documented in this **Federal Register** notice. Thus, the TTIP negotiations had no relationship to Poland's food regulatory system or this **Federal Register** notice.

Expected Costs

FSIS updated the expected costs and benefits sections of this notice to reflect more recent trade data than FSIS used for the preliminary regulatory impact analysis (81 FR 23194, April 20, 2016). Poland is the largest poultry producer within the European Union (EU). From 2006 to 2019, Poland sharply increased its poultry production and exports. According to USDA's Foreign Agricultural Service, Poland's poultry exports exceeded 1.3 million metric tons in 2019, a 12-percent increase over 2018.² In 2019, a high pathogenic avian influenza (HPAI) outbreak led to several countries imposing import bans on Polish poultry, adversely affecting Polish poultry exports in 2020. Thus, the Government of Poland is trying to "open new market opportunities, including United States market access."³

Poland's poultry production consists of 85 percent young chickens ("broilers"), 14 percent young turkey, and about one

² See: USDA FAS GAIN Report: Poultry and Products Annual, Poland. March 26, 2020. Report Number PL2020-0012 Prepared by Piotr Rucinski At: [https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?file Name=Poultry and Products Annual_Warsaw_Poland_03-18-2020](https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Poultry%20and%20Products%20Annual_Warsaw_Poland_03-18-2020)

³ Ibid.

percent other poultry species such as duck and geese.^{4,5}

Currently, almost 70 percent of Polish chicken meat exports go to neighboring EU markets, particularly to the United Kingdom, Germany, and France.⁶ For Poland to export poultry to the United States, it must be export-eligible, export-capable, and price-competitive. After comparing Poland's price competitiveness with the United States, Chile, and Canada, FSIS estimated that the maximum potential Polish poultry products exports to the United States is expected to be between 19,400 MT to 31,600 MT.⁷ This means, at a maximum, the total United States poultry supply will increase only between 0.10 percent and 0.16 percent (19,400 MT to 31,600 MT from Poland compared to a United States slaughter volume of 20.1 million MT in 2020)⁸, leaving the total United States poultry supply almost unchanged. Thus, Poland's poultry exports to the United States are expected to minimally change domestic poultry prices, not enough to alter the United States poultry market.

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.

⁷ FSIS estimated the maximum potential Polish poultry products by identifying poultry products imported from Canada and Chile (these two countries account for more than 97% of the poultry products imported to the United States). FSIS assumed the potential volume of Polish poultry products that would be exported to the U.S. was equal to the volume of Polish poultry products that had a unit price lower than Chile's and Canada's poultry products unit prices (from 2018 and a 3-year average).

FSIS then used the volume of U.S. imports for these products (based on 2018 data and a 3-year average) to estimate the maximum potential Polish poultry exports.

⁸ USDA, Foreign Agricultural Service, Production, Supply and Distribution. <https://apps.fas.usda.gov/psdonline/app/index.html#/app/advQuery>

For 2020 U.S. Production, please see November 2020 WASDE Report at: <https://www.usda.gov/oce/commodity/wasde> The numbers have been converted to Metric Ton.

The above cost analysis is based on Poland's maximum potential poultry exports. Currently, however, 24 establishments in Poland intend to export poultry products to the United States.⁹ The total processing capacity of these 24 establishments is far less than Poland's total poultry export capacity. With minimal price changes expected in United States poultry products markets, Poland's eligibility to export poultry products to the United States should not have a negative effect on United States consumers.

Expected Benefits

The volume of trade stimulated by Poland's eligibility to export poultry products to the United States is likely to be small and is expected to have little or no effect on United States poultry supplies or poultry prices. United States consumers, however, are expected to enjoy more choices when purchasing poultry products. This equivalence determination will, therefore, expand choices for United States consumers and promote economic competition.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register_. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide

⁹ Source: Correspondence with the government of Poland.

information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

<https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

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Paul Kiecker,
Administrator.

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